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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/905,189 | 07/13/2001 | Guang-Jong Jason Wei | 163.1438US01 | 3059 |

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| EXAMINER | |
|---|---|
| PAK, JOHN D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/905,189 | WEI ET AL. | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 May 2005 and 31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8,11,12,15-20,24-33 and 35-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12,15-20,24-33 and 35-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/2005 has been entered.

This application continues to be examined under the requirement that was made under 35 USC 121 to elect a single disclosed species comprising mono or diester dicarboxylates such as monomethyl malonate (Office action of 9/23/2002). The requirement is maintained and repeated herein. In applicant's reply of 1/15/2003, applicant elected with traverse sebacic acid esters and adipic acid esters. This election carries over in this RCE in the absence of contrary indication by applicant. The pending claims 1-8, 11-12, 15-20, 24-33 and 35-47 will therefore continue to be examined to the extent that they read on the elected subject matter of record, i.e. sabacic acid esters and adipic acid esters.

Applicant is **again** advised to check the nomenclature of the substance fully recited on line 3 of claim 19. It appears that the brackets may be not be properly placed in position.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11-12, 15-20, 24-25 and 29-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Carr et al. (WO 95/34537) for the reasons of record.

Carr et al. explicitly teach an aqueous disinfectant solution that contains a monoester of a dicarboxylate such as a mono-$C_{1-4}$ alkyl ester of adipic acid (when x = 4), a peracid thereof, and hydrogen peroxide. See p. 3, lines 7-20; p. 4, lines 7-17 and 34-37; p. 10, lines 17-38. The monoester is present from about 0.05 to 10%, including 1 to 9% by weight (p. 4, lines 34-37). The hydrogen peroxide is present from 0.5 to 15%, including 1 to 10% by weight (p. 5, lines 1-6). Stabilizing agent such as EDTA and HEDP (hydroxyethylidenediphosphonic acid) may be present at 0.25 to 1.5 wt% (p. 5, lines 13-28). Choice of organic sulfonic acid such as methane sulfonic acid to provide acidic pH to the aqueous disinfectant solution is disclosed (p. 8, line 38). A method of making the aqueous solution is disclosed wherein an aqueous solution of a mono-$C_{1-4}$

alkyl ester of a dicarboxylate such as adipic acid (x = 4) is contacted with a peroxide such as hydrogen peroxide under pH less than 4 obtained by using an acid such as methane sulfonic acid (p. 8, lines 11-38; p. 9, lines 31-33). Equilibrium may be obtained after 1 to 30 days (p. 9, lines 29-30). Dilution of the equilibrated solution is disclosed (p. 10, lines 4-10).

The claims are thereby anticipated. The claim feature of "free of added strong inorganic acid" is met by Carr et al. because organic acids such as methane sulfonic acid are explicitly disclosed. The claim feature of 2 wt% mono-$C_{1-4}$ alkyl ester of adipic acid is taught by Carr et al. from their disclosure of 1 to 9 wt% mono-$C_{1-4}$ alkyl ester of adipic acid. 2 wt% is clearly envisaged by the 1 to 9 wt% disclosure. The claim feature of 2 wt% or 1 to 4 wt% hydrogen peroxide is taught by Carr's 1 to 10 wt% hydrogen peroxide disclosure. 2 wt% is clearly envisaged by the 1 to 10 wt% disclosure. The claimed weight percentage feature for water is also taught by Carr et al. from the weight percentages disclosed for all other composition components. Even 95 wt% water or more is clearly taught since the combined amounts of the necessary composition components are less than 5 wt% at the low end of Carr's range. Removing a portion of the retained hydrogen peroxide and mono-ester dicarboxylate from the vessel for diluting is taught since diluting is taught by Carr et al. "A portion" includes some or all of the vessel contents. Batch-wise adding of reaction ingredients is clearly taught by Carr

et al. (p. 8, lines 11-33; see Example 1 on pages 11-13). Batch-wise removing a portion for diluting is also taught (p. 10, lines 4-10).

As for the claim-recited antimicrobial feature, it is the Examiner's position that such activity would necessarily have been present in the disinfectant solution disclosed by Carr et al. because the presence of the same exact ingredients at the same percentages would necessarily have provided the prior art solution with the same activity.

Applicant's arguments and the declaration by Dr. Hei (5/31/2005) have been given due consideration, but they were deemed unpersuasive. Applicant argues and declares that Carr's methane sulfonic acid is actually a strong inorganic acid, which must be excluded in the claimed invention. Applicant points to the specification disclosure that states that sulfuric acid is a strong inorganic acid. Applicant takes this as evidence that sulfonic acids are inorganic, too.

The Examiner cannot agree. First, there is the verbatim disclosure by Carr et al. at page 8, lines 37-38, "a strong acid, for example sulphuric acid, phosphoric acid **and organic sulphonic acids such as methane sulphonic acid** ...." (emphasis added). Carr et al. clearly states that methane sulfonic acid is an organic acid, in contrast to the inorganic sulfuric acid. Second, methane sulfonic acid clearly meets the definition of "organic" in the U.S. Patent classification system because methane sulfonic acid contains a carbon bonded to a hydrogen, wherein the methane sulfonic acid does not

belong to the specifically excluded compounds in the definition. See the definition of "ORGANIC" in the December 202 edition of "Classification Definitions," provided herewith.

Therefore, there is sufficient contrary evidence to rebut applicant's argument and declaration that Carr's "organic sulphonic acids" such as methane sulfonic acid is inorganic. Carr's organic sulfonic acids are organic acids, and they therefore are not excluded by applicant's claimed invention.

For the foregoing reasons, the claims are thereby rejected as being anticipated.

Claims 1-8, 11-12, 15-20, 24-33 and 35-47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (WO 95/34537) in view of Hei et al. (US 6,593,283) and Chemical Abstracts 134:97683 for the reasons of record.

Teachings of Carr et al. were discussed above in the preceding ground of rejection and that discussion is incorporated herein by reference. Additionally, the following further teachings are noted for this ground of rejection. Carr et al. further teach that their disinfectant composition can be employed to treat a wide range of substrates such as hard surfaces such as ceramics or glass, contaminated articles intended for reuse in the food processing, catering, domestic or hospital environments, (p. 11, lines 1-18). Disinfection of process waters in food processing industries such as brewing, wine making and alcohol distilling industries is disclosed (p. 10, lines 25-29).

Hei et al. disclose an antimicrobial composition that contains water (as "diluting solvent"), diesters such as dimethyl dimethyl adipate, diethyl adipate, dibutyl adipate (as "antimicrobially active solvent"), and hydrogen peroxide (as "additional antimicrobial agent"). See column 2, lines 25-52; column 3, line 50 to column 8, line 40; claims 10, 14, 27, 28-37. Greater than 1-log order reduction in the population of bacteria or spores of *Bacillus cereus* or *Chaetomium funicola* within 10 seconds at 60° C is disclosed (column 3, lines 10-42; column 3, line 50 to column 4, line 33). Use in a wide range of applications such as hard surface cleaners, cold aseptic packaging treatments, food, food equipment, bottles, and tanks/pumps/lines is disclosed (column 12, line 16 to column 13, line 13). Although the "antimicrobially active solvent" component, which encompasses diesters of adipic ester, is disclosed to be present in an amount that is at least 5 wt% (column 7, lines 50-52), but Hei's composition is clearly intended to be diluted before use (column 11, lines 12-30). The diluted use-composition is taught to contain 0.01 to 50 wt% "antimicrobially active solvent" (column 11, lines 22-24).

Chemical Abstracts 134:97683 is cited to establish that peracetic acid is known to have activity against *Chaetomium funicola* and *Arthrinium sacchari*.

It is noted that claims 1-5, 11-12, 15-20, 24-25 and 29-32 were already rejected over Carr et al. under section 102. Therefore, with respect to those claims, there is no patentable difference between the claims and Carr et al. Alternatively, to the extent that applicant would argue lack of explicit teaching for the claimed features, "free of added

strong inorganic acid," composition component percentages, proportions or antimicrobial activity, the following comments are noted. The claim feature, "free of added strong inorganic acid" is amply suggested by Carr et al. because organic acids such as methane sulfonic acid are explicitly disclosed. The claim feature, 2 wt% mono-$C_{1-4}$ alkyl ester of adipic acid, is amply suggested by Carr et al. from their disclosure of 1 to 9 wt% mono-$C_{1-4}$ alkyl ester of adipic acid. 2 wt% is clearly within the 1 to 9 wt% disclosure. The claim feature, 2 wt% or 1 to 4 wt% hydrogen peroxide, is taught by Carr's 1 to 10 wt% hydrogen peroxide disclosure. 2 wt% is clearly within the 1 to 10 wt% disclosure. The claimed weight percentage feature for water is also suggested by Carr et al. from the weight percentages disclosed for all other composition components. Even 95 wt% water or more is clearly taught since the combined amounts of the necessary composition components are less than 5 wt% at the low end of Carr's range.

As for the claim-recited antimicrobial feature, it is the Examiner's position that such activity would necessarily have been present in the disinfectant solution disclosed by Carr et al. because the presence of the same exact ingredients at the same percentages would necessarily have provided the prior art solution with the same activity. Additionally, similar solutions containing diesters of adipic acid + hydrogen peroxide are also shown to possess the same type of activity against *Bacillus cereus* and *Chaetomium funicola* (Hei et al.). Further, peracetic acid is known to possess activity against *Arthrinium sacchari*. Therefore, one of ordinary skill in the art would

have recognized that solutions that contain known antimicrobially active substances such as percarboxylic acids (from monoester of adipic acid + hydrogen peroxide), hydrogen peroxide per se, and/or mixture of diester of adipic acid + hydrogen peroxide, would have been expected to possess similar activity against the same microorganisms.

The motivation to add or utilize diesters of adipic acid or diesters of another dicarboxylic acid is provided by Hei's teachings, wherein such diesters are taught as "antimicrobially-active solvents." Adjustment of the concentration amounts to that of the claimed amounts is fairly suggested by the dilution-for-use teachings of Carr et al. and Hei et al. The various substrates to be disinfected and cold aseptic bottling of food or beverages are suggested by the teachings of broad disinfecting use taught by Carr et al. and the same specific teachings by Carr et al. for the similarly structured mixtures of diesters of adipic acid + hydrogen peroxide.

Applicant's arguments and the declaration by Dr. Hei (5/31/2005) have been given due consideration, but they were deemed unpersuasive. Applicant argues and declares that Carr's methane sulfonic acid is actually a strong inorganic acid, which must be excluded in the claimed invention. Applicant points to the specification disclosure that states that sulfuric acid is a strong inorganic acid. Applicant takes this as evidence that sulfonic acids are inorganic, too.

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**organic sulphonic acids such as methane sulphonic acid** ...." (emphasis added). Carr et al. clearly state that methane sulfonic acid is an organic acid, in contrast to the inorganic sulfuric acid. Second, methane sulfonic acid clearly meets the definition of "organic" in the U.S. Patent classification system, because methane sulfonic acid contains a carbon bonded to a hydrogen and methane sulfonic acid does not belong to the specifically excluded compounds in the definition. See the definition of "ORGANIC" in the December 202 edition of "Classification Definitions," provided herewith.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
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